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FORM PTO-	FORM PTO-1449/A and B (Modified)				Not yet assigned	ATTY.'S DOCKET NO.: C1040.70012US00		
1	MATION DIS			FILING DATE:	Herewith CONFIRMATION NO.: Not yet assigne			
STATE	STATEMENT BY APPLICANT			APPLICANT:	Heather Lynn DAVIS et al.			
Sheet	1	of	4	GROUP ART UNIT:	1632	EXAMINER: Not yet assigned Anne-Marie Falk, Ph.D.		

U.S. PATENT DOCUMENTS

Examiner's	Cite	U.S. Patent Doc	ument	Name of Patentee or Applicant of Cited	Date of Publication or of issue	
Initials†	No.	Number	Kind Code	Document .	of Cited Document MM-DD-YYYY	
	*A1	5,593,972		Weiner et al.	01/14/1997	
	*A2	5,620,896		Herrmann et al.	04/15/1997	
	*A3	5,643,578		Robinson et al.	07/01/1997	
	*A4	5,714,316		Weiner et al.	02/03/1998	
	*A5	5,736,524		Content et al.	04/07/1998	
	*A6	5,814,617		Hoffman et al.	09/29/1998	
	*A7	5,256,767		· Salk et al.	10/26/1993	
	*A8	5,256,553		Overell et al.	10/26/1993	
	*A9	5,780,448		Davis	07/14/1998	
	*A10	5,856,462		Agrawal	01/05/1999	
	*A11	5,565,293		Gluck et al.	10/15/1999	
	*A12	5,972,346		Hauser et al.	10/26/1999	
	*A13	5,981,274		Tyrrell et al.	11/09/1999	
	*A14	5,565,203		Glück et al.	10/15/1996	
	*A15	5,972,346		Hauser et al.	10/26/1999	
	*A16	5,679,647	B1	Carson ct al.	10/21/1997	
	*A17	5,804,566	B1	Carson et al.	09/08/1998	
	*A18	5,830,877	B1	Carson et al.	11/03/1998	
	*A19	5,985,847	B1	Carson et al.	11/16/1999	

## FOREIGN PATENT DOCUMENTS

Examiner's	Cite	For	reign Patent Docu	ment	Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
Initials†	No.	Office/ Country	Number	Kind Code			
	*B1	wo	93/15207	Al		08/05/1993	
	*B2	wo	88/06185	A1		08/25/1988	
	*B3	WO	92/06212	A1		04/16/1992	
	*B4	CA	1 169 793			06/26/1984	
	*B5	wo	90/11092	A1		10/04/1990	-
	*B6	wo	95/05853	A1		03/02/1995	

## OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's	Cite	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the	Translation				
Initials†	No	item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.					
	*C1	Agrawal, S., et al., "Pharmacokinetics of Antisense Oligonucleotides", <i>Clin Pharmacokinet.</i> , 7-16, (1995)					
	*C2	Cattaneo, R., et al., "Signals regulating hepatitis B surface antigen transcription", <i>Nature</i> , 305:336-338, (1983)					
	*C3	Cowdery, J., et al., "Bacterial DNA Induces NK Cells to Produce 1FN-γ In Vivo and Increases the Toxicity of Lipopolysaccharides" <i>Bacterial DNA</i> , (1996)					

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMF/

Receipt date: 08/20/2003 10644267 - GAU: 1632

	O-1449/A and B (M		i)	APPLICATION NO.:	Not yet assigned		ATTY.'S DOCKET NO.: C1040.70012US00		
1	RMATION DI			FILING DATE:	FILING DATE: Herewith CONFIRMATION NO.: No				
STATEMENT BY APPLICANT				APPLICANT:	Heather Lynn DAVIS et al.				
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OTHER ART—NON PATENT LITERATURE DOCUMENTS

Examiner's Initials†	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	*C4	Davis, H., et al., "Direct gene transfer into skeletal muscle in vivo: Factors affecting efficiency of transfer and stability of expression" <i>Human Gene Therapy</i> , 4: 151-159, (1993)	
_	*C5	Davis, H.,et al., "DNA-based immunization induces continuous secretion of hepatitis B surface antigen and high levels of circulating antibod" <i>Human Molecular Genetics</i> , 2:1847-1852, (1993)	
	*C6	Davis, H.,et al., "DNA vaccine for hepatitis B: Evidence for immunogenicity in chimpanzees and comparison with other vaccines, <i>Proc Natl Acad, Sci</i> , 93:7213-7218, (1996)	
	*C7	Fujieda, S., et al., "Effect of OK-432 on Cytotoxic Activity in Cancer patients without Tumor Burden", Anticancer Research, 12:1941-1946, (1992)	
	*C8	Fujisawa T et al, "Serial changes in titers of antibody to hepatitis B surface antigen after immunization of infants born to mothers with hepatitis B e antigen". <i>Pediatr. Gastroenterol Nutr</i> , 23:270-274, (1996)	
	*C9	Fuller, D., et al., "Induction of immunodeficiency virus-specific immune responses in rhesus monkeys following gene Gun-mediated DNA vaccination", J. Med. Primates, 25:236-241, (1996)	
	*C10	Fynan, E., et al., "DNA vaccines: Protective immunizations by parentaeral, mucosal, and genegun inoculations", Proc. <i>Natl. Acad. Sci.</i> , 90:11478-11482, (1993)	
	*C11	Gao, W., et al., "Phosphorothioate Oligonucleotides are inhibitors of human DNA polymerases and Rnase H: implications for antisense technology", 223-229, (1991)	
	*C12	Jones, T., et al., "Synthetic oligodeoxynucleotiedes containing CpG motifs enhance immunogenicity of a peptide malaria vaccine in Aotus monkeys", <i>Vaccine</i> , 17:3065-3071, (1999)	
	*C13	Karlin, S., et al., "Why is CpG Suppressed in the Genomes of Virtually All Small Eukaryotic Viruses but Not in Those of large Eukaryotic Viruse?", Journal of Virology, 2889-2897, (1994)	
	*C14	Kataoka, T., et al., "Antitumor Activity of Synthetic Oligonucleotides with Sequences from cDNA Encoding Proteins of Mycbacterium vobis BCG", Jpn. J. Cancer Res., 83:244-247, (1992)	
	*C15	Krieg, A., et al., "CpG motifs in bacterial DNA trigger direct B-cell activation", Nature, 374:546-549, (1995)	
	*C16	Lee, PI., et al., "Long-term efficacy of recombinant hepatitis B vaccine and risk of natural infection in infants born to mothers with hepatitis B e antigen." <i>J. Pediatr</i> , 126: 716-721, (1995)	
	*C17	Li, Z., et al., "Desmin sequence elements regulating skeletal muscle-specific expression in transgenic mice", <i>Development</i> , 117:947-959, (1993)	
	*C18	LIU, H., et al., "Immunostimulatory CpG Oligodeoxynucleotides Enhance the Immune Response to Vaccine Strategies Involving Granulocyte-Machrophate colony-Stimulating Factor", <i>Blood</i> , 92:10:3730-3736, (1998)	
	*C19	LUTYNSKI R. and Juszczyk R, "The level of anti-HBs in blood serum of persons selected from a group of Krakow inhabitants" Folia Med. Cracov., 38: 63-68, (1997)	
	*C20	Mcintyre, K., et al., "A Sense Phosphorothioate Oligonucleotide Directed to the Initiation Codon of Transcription Factor NF-kB p65 Causes Sequence-Specific Immune Stimulation", Antisense&Nucleic Acid Drug Development, 3:309-322, (1993)	
	*C21	MANZEL, L., et al., "Lack of Immune Stimulation by Immobilized CpG- Oligodeoxynucleotide", Antisense&Nucleic Acid Drug Development, 9:459-464, (1999)	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /AMF/

FORM PT	O-1449/A and B (M	/lodifie	d)	APPLICATION NO.: Not yet assigned		ATTY.'S DOCKET NO.: C1040.70012US00		
1	RMATION DI			FILING DATE:	Herewith	CONFIRMATION	NO.: Not yet assigned	
STATEMENT BY APPLICANT				APPLICANT:	Heather Lynn DAVIS et al.			
Sheet 3 of 4		GROUP ART UNIT: 1632		EXAMINER:	Not yet assigned			

		OTHER ART —NON PATENT LITERATURE DOCUMENTS (continued)	
Examiner's Initials†	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	*C22	MOJCIK, C., et al., "Administration of a Phosphorothioate Oligonucleotide Antisense Murine Endogenous Retroviral MCF env Causes Immune Effects in Vivo in a Sequence-Specific Manner", Clinical Immunology and ImmunoPathology, 67:2:130-136, (1993)	
	*C23	PISETSKY, D., et al., "Immunologic Consequences of Nucleic Acid Therapy",  Antisense&Nucleic Acid Drug Development, 5:219-225, (1995)	
	*C24	PRINCE, A., et al., "Successful nucleic acid based immunization of newborn chimpanzees against hepatitis B virus", <i>Vaccine</i> , 15:8:916-919, (1997)	
	*C25	RAZ, E.,et al., "Intradermal gene immunization: The possible role of DNA utake in the induction of cellular immunity to viruses", <i>Proc. Natl. Acad. Sci.</i> , 91:9515-9523, (1994)	
	*C26	ROBINSON, H., "Nucleic acid vaccines: an overview", Vaccine, 15:8:785-787, (1997)	
	*C27	SANDS, H., et al., "Biodistribution and Metabolism of Internally 3H-Labeled Oligonucleotides.  I. Comparison of a Phosphodiester and a Phosphorothioate", <i>The American Society for Pharmacology</i> , 45:932-943, (1994)	
	*C28	STEIN, C., et al., "Antisense Oligonucleotides as Therapeutic Agents - Is the bullet Really Magical", Science, 261:1004-1012, (1993)	
	*C29	THOMSEN, D., et al., "Promoter-regulatory region of the major immediate early gene of human cytomegalovirus", Proc. Natl. Acad. Sci., 81:659-663, (1984)	
	*C30	TOKUNAGA, T., et al., "Antitumor Activity of Deoxyribonucleic Acid Fraction From Mycobacterium bovis BCG. I. Isolation, Physicochemical Characterization, and Antitumor Activity", JNC1, 72:955-962, (1984)	
	*C31	ULMER, J., et al., "Heterologous protection Against Influenza by Injection of DNA Encoding a Viral Protein", Science, 259:1745-1749, (1993)	
	*C32	VALENZUELA, P., et al., "Synthesis and assembly of hepatitis B virus surface antigen particles in yeast", <i>Nature</i> , 298:347-350, (1982)	
	*C33	WANG, B., et al., "Gene inoculation generates immune responses against human immunodeficiency virus type 1", <i>Proc Natl. Acad. Sci.</i> , 90:4156-4160, (1993)	
	*C34	YASWEN, P., et al., "Effects of Sequences of Thioated Oligonucleotides on cultured Human Mammary Epithelial Cells", Antisense Research and Development, 3:67-77, (1993)	
	*C35	ZELPHATI, O., et al., "Inhibition of HIV-I Replication in Cultured Cells with Antisense Oligonucleotides Encapsulated in Immunoliposomes, Antisense Research and Development, 3:323-338, (1993)	
***************************************	*C36	MUCHetal	•••••
	*C37	SHIH et al	
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	*C38	11.4.4.4.6.6.6.6.6.4.4.4.	
	*G29	SZMONESS et al.	
000000000000000000000000000000000000000	*C40	DÖHM et al.	000000000000000000000000000000000000000
	*C41	CALANDRA, G.B. et al., Recommendations for Prevention of Hepatitis B with Vaccine, Hepatitis B Vaccines in Clinical Practice, Merck Research Laboratories, pages 1-16, 1993	
	*C42	CHAMBON, P., ADN: sur la piste du vaccine génétique, Sciences et Avenir, September 1993, pages 22-25	

Receipt date: 08/20/2003 10644267 - GAU: 1632

FORM PTO	D-1449/A and B (	Modifie	d)	APPLICATION NO.: Not yet assigned		ATTY.'S DOCKET NO.: C1040.70012US00		
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STATEMENT BY APPLICANT			APPLICANT:	Heather Lynn DAVIS et al.				
Sheet	4	of	4	GROUP ART UNIT:	1632	EXAMINER:	Not yet assigned	

OTHER ART —NON PATENT LITERATURE DOCUMENTS (continued)

Examiner's Initials†	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue			
<u>'</u>		number(s), publisher, city and/or country where published.	(Y/N)		
	*C43	HAYES, J.R. et al., Particle-mediated nucleic acid immunization, Journal of Biotechnology 44, 1996, pages 37-42			
-	*C44	KUHÖBER, A., et al. DNA Immunization Induces Antibody and Cytotoxic T Cell Responses to Hepatitis B Core Antigen in H-2 <sup>b</sup> Mice,			
		The American Association of Immunologists, 1996, pages 3687-3695			
	*C45	LEBORGNE, S. et al., In Vivo Induction of Specific Cytotoxic T Lymphocytes in Mice and Rhesus Macaques Immunized with DNA (January 1998) Virology 240(2):			
	*C46	Vector Encoding an HIV Epitope Fused with Hepatitis B Surface Antigen, Virology 240, 304-315, 1998, Article No. VY978942			
	*C47	WOLFF et al., Direct Gene Transfer into Muse Muscle in Vivo, Science, Vol. 247, March 1990, pages 1465-1468			
	*C48	RAZ, E. et al., "Systemic immunological effects of cytokine genes injected into skeletal muscle", <i>Proc. Natl. Acad. Sci. USA</i> , May 1993, Pages 4523-4527, Vol. 90			
	*C49	TANG, D. et al., "Genetic immunization is a simple method for eliciting an immune response", Nature, March 12, 1992, Pages 152-154, Vol. 356			
	*C50	CHATTERGOON et al., Genetic Immunization: A New Era in Vaccines and Immune Therapeutics, FASEB Journal, Vol. 11, pages 753-763. (1997)	-		

EXAMINER /Anne Marie Falk/	DATE CONSIDERED 06/22/2010
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<sup>†</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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<sup>\*</sup>a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. 09/146,072, filed September 2, 1998 and now pending, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).